Docket No.: 1173-1034PUS2

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Mario H. Skiadopoulos et al.

Application No.: 10/667,141

Filed: September 18, 2003

For: RECOVERY OF RECOMBINANT HUMAN

PARAINFLUENZA VIRUS TYPE 2 (HPIV2) FROM cDNA and USE OF RECOMBINANT HPIV2 IN IMMUNOGENIC COMPOSITIONS AND AS VECTORS TO ELICIT IMMUNE RESPONSES AGAINST PIV AND OTHER

**HUMAN PATHOGENS** 

Confirmation No.: 7197

Art Unit: 1648

Examiner: Agnieszka Boesen

## DECLARATION REGARDING DEPOSIT OF MICROORGANISMS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Madam,

I, Michael Shmilovich, do hereby declare as follows:

I am an agent of The Government of the United States of America, as represented by the Secretary of the Department of Health and Human Services, the assignee of the above-identified application, with an office at 6011 Executive Blvd., Suite 325, Rockville, Maryland 20852. I am empowered to execute documents on behalf of the Assignee.

Cultures of the following microorganisms were deposited under the terms and conditions of the Budapest Treaty at the American Type Culture Collection, 10801 University Blvd., Manassas, Virginia 20110-2209, on the indicated dates.

Declaration re: deposit of microorganisms

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Deposit
Date

Scientific

Description

Depository Designation

PTA-2419

August 24, 2000

Human Parainfluenza Virus Type 3

(cold-passage 45)

HPIV3 cp45 JS strain (lot HP13-3)

The above depository affords permanence of the deposits and ready accessibility thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of said patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. 122, and (b) that the above-mentioned cultures will be available to the public without restriction upon the granting of a patent.

These deposits are referred to on page 38, lines, in paragraph 90 of the above-identified application and are identified by deposit number, name and address of the depository. The taxonomic description to the extent available is included in the specification.

The undersigned hereby assures the permanent availability of said cultures to the public through the above depository and in the event that any of the strains should become non-viable, mutate or inadvertently be destroyed, the undersigned will replace the strains at the above-mentioned depository. The undersigned further assures that all restrictions on the availability to the public of the above-mentioned cultures will be irrevocably removed upon the granting of a patent.

The above-mentioned deposits will be maintained (1) for thirty (30) years from the date of deposit, (2) for five (5) years after the last request for the deposit at the depository, or (3) for the enforceable life of any patent which issues from the above-identified application, whichever is longer.

Declaration re: deposit of microorganisms

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Attached hereto is a copy of paper(s) from said depository evidencing the agreement

between said depository and the depositor.

I hereby declare that all statements made herein of my own knowledge are true and that all

statements made on information and belief are believed to be true; and further that these statements

were made with the knowledge that willful false statements and the like so made are punishable by

fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that

such willful false statements may jeopardize the validity of the application or any patent issued

thereon.

Date: 12 Au

Michael Shmilovich

National Institutes of

Health/Office of Technology Transfer

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10801 University Blvd ♦ Managemes, VA 20110-2209 ■ Telephone: 703-365-2700 ● FAX: 703-365-2745

## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

National Institutes of Health Atm: Mario Skiadopoulos 7 Center Drive, Bldg. 7/ Rm 138 Bethesda, MD 20892

Deposited on Behalf of: NIAID, NIH

Identification Reference by Depositor: Human Parainfluenza Virus Type 3 (cold-passage 45): HPIV3 cp45 JS strain (lot HP13-3) Patent Deposit Designation PTA-2419

The deposit was accompanied by: \_\_ a scientific description a proposed taxonomic description indicated above.

The deposit was received August 24, 2000 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested October 27, 2000. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manussas, VA 20110-2209 USA.

Signature of person-having authority to represent ATCC:

Frank Simione, Director, Patent Depository

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Date: November 20, 2000

ce: Jeffrey J. King